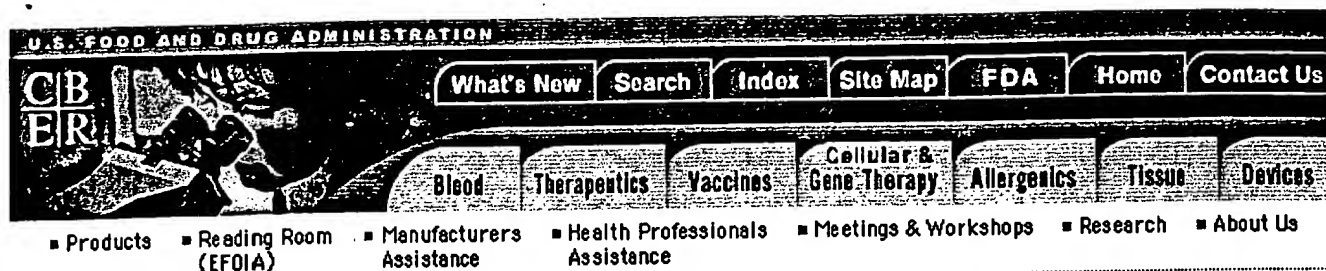


## Product Approval Information - Licensing Action

Proper name: **Botulinum Toxin Type A**  
 Tradename: **BOTOX**  
 Manufacturer: **Allergan, Inc., Irvine, CA, License #1145**  
 Indication for Use: **Treatment of cervical dystonia.**  
 Approval Date: **12/21/2000**  
 Type of submission: **Biologics license supplement**

Approval Letter ([PDF](#)), ([Text](#))

*Last Updated: 3/5/2001*



## Product Approval Information - Licensing Action

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Proper name: **Botulinum Toxin Type B**

Tradename: **MYOBLOC**

Manufacturer: **Elan Pharmaceuticals, South San Francisco, CA, License #1579**

Indication for Use: **Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain.**

Approval Date: **12/08/2000**

Type of submission: **Biologics license application**

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Approval Letter ([Text](#)), ([PDF](#))

Labeling ([PDF](#))

Statistical Review ([PDF](#))

Supplemental Clinical Review ([PDF](#))

Chemistry, Manufacturing, and Controls Section Review ([PDF](#))

Clinical Review ([PDF](#))

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*Last Updated: 7/23/2001*



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## Product Approval Information - Licensing Action

Proper name: **Botulinum Toxin Type A**

Tradename: **BOTOX COSMETIC**

Manufacturer: **Allergan, Inc, Irvine, CA, License #1145**

Indication for Use: **Temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients  $\leq$  65 years of age**

Approval Date: **4/12/2002**

Type of submission: **Biologics license supplement**

[Approval Letter \(Text\)](#)

[Label - \(PDF\)](#)

[Talkpaper](#)

*Last Updated: 4/15/2002*